

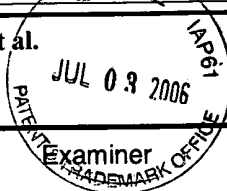
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TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT (Under 37 CFR 1.97(b) or 1.97(c))				Docket No. 16096	
In Re Application Of: Richard James Lewis et al.					
Application No. 10/537,088	Filing Date June 2, 2005	Examiner Unassigned	Customer No. 23389	Group Art Unit Unassigned	Confirmation No. 9222
Title: NOVEL X-CONOTOXIN PEPTIDES (-II)					
<p>Address to: Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450</p> <p><b>37 CFR 1.97(b)</b></p> <p>1. <input checked="" type="checkbox"/> The Information Disclosure Statement submitted herewith is being filed within three months of the filing of a national application other than a continued prosecution application under 37 CFR 1.53(d); within three months of the date of entry of the national stage as set forth in 37 CFR 1.491 in an international application; before the mailing of a first Office Action on the merits, or before the mailing of a first Office Action after the filing of a request for continued examination under 37 CFR 1.114.</p> <p><b>37 CFR 1.97(c)</b></p> <p>2. <input type="checkbox"/> The Information Disclosure Statement submitted herewith is being filed after the period specified in 37 CFR 1.97(b), provided that the Information Disclosure Statement is filed before the mailing date of a Final Action under 37 CFR 1.113, a Notice of Allowance under 37 CFR 1.311, or an Action that otherwise closes prosecution in the application, and is accompanied by one of:</p> <p><input type="checkbox"/> the statement specified in 37 CFR 1.97(e);</p> <p><b>OR</b></p> <p><input type="checkbox"/> the fee set forth in 37 CFR 1.17(p).</p>					

**TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT**  
(Under 37 CFR 1.97(b) or 1.97(c))

Docket No.  
16096

In Re Application of: **Richard James Lewis et al.**



Application No.  
10/537,088

Filing Date  
June 2, 2005

Examiner  
Unassigned

Customer No.  
23389

Group Art Unit  
Unassigned

Confirmation No.  
9222

Title: **NOVEL X-CONOTOXIN PEPTIDES (-II)**

**Payment of Fee**

(Only complete if Applicant elects to pay the fee set forth in 37 CFR 1.17(p))

- ☐ A check in the amount of \_\_\_\_\_ is attached.
- ☒ The Director is hereby authorized to charge and credit Deposit Account No. 19-1013/SSMP as described below.
- ☐ Charge the amount of \_\_\_\_\_
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Dated: June 28, 2006

Xiaochun Zhu  
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(516) 742-4343

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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

**Applicants:** Richard James Lewis et al.

**Examiner:** Unassigned

**Serial No:** 10/537,088

**Art Unit:** Unassigned

**Filed:** June 2, 2005

**Docket:** 16096

**For:** NOVEL  $\chi$ -CONOTOXIN PEPTIDES (-II)

**Dated:** June 28, 2006

**Confirmation No:** 9222

Mail Stop Amendment  
Commissioner for Patents  
P. O. Box 1450  
Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT**

Sir:

In accordance with 37 C.F.R. §§1.97 and 1.98, it is requested that the following references, which are also listed on the attached Form PTO-1449, be made of record in the above-identified case.

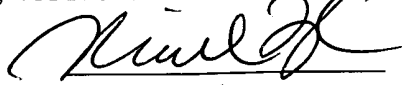
1. International Publication No. WO 98/22126, published May 28, 1998;

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**CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)**

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on June 28, 2006.

Dated: June 28, 2006

  
Xiaochun Zhu

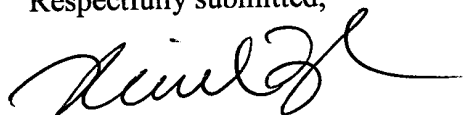
2. International Publication No. WO 91/07980, published June 13, 1991;
3. International Publication No. WO 96/14079, published May 17, 1996;
4. International Publication No. WO 96/40064, published December 19, 1996;
5. International Publication No. WO 98/05309, published February 12, 1998;
6. International Publication No. WO 98/02148, published January 22, 1998;
7. International Publication No. WO 98/51668, published November 19, 1998;
8. International Publication No. WO 97/30997, published August 28, 1997;
9. International Publication No. WO 97/01351, published January 16, 1997;
10. United States Patent No. 6,767,896 B1, dated July 27, 2004, issued to McIntosh et al.;
11. United States Patent No. 6,794,361 B1, dated September 21, 2004, issued to Lewis et al.;
12. United States Patent No. 5,587,454, dated December 24, 1996, issued to Justice et al.;
13. United States Patent Application Publication No. 2005/0054827 A1, dated March 10, 2005 to Lewis et al.;
14. Bowersox, S.S. et al., "Selective N-Type Neuronal Voltage-Sensitive Calcium Channel Blocker, SNX-111, Produces Spinal Antinociception in rat Models of Acute, Persistent and Neuropathic Pain", *J. Pharmacol Exp. Ther.*, 279 (3): 1243-1249 (1996);
15. Krames, Elliot S. et al., "Intrathecal D-Ala<sup>2</sup>-D-Leu<sup>5</sup>-enkephalin (DADL) Restores Analgesia in a Patient Analgetically Tolerant to Intrathecal Morphine Sulfate", *Pain*, 24: 205-209 (1986);
16. Takagi, H. et al., "Analgesic Effect of L-threo-3-4-dihydroxyphenylserine (L-DOPS) in Patients with Chronic Pain", *European Neuropsychopharmacology*, 6: 43-47 (1996);
17. Eisenach, C. et al., "Cerebrospinal Fluid Norepinephrine and Acetylcholine Concentrations During Acute Pain", *Anesth Analg*, 82: 621-626 (1996);
18. Dubner, R. et al., "The Neurobiology of Pain and Its Modulation", *The Clinical Journal of Pain*, 5(Suppl 2): S1-S6 (1989);

19. Dyck, P.J et al., "New Understanding and Treatment of Diabetic Neuropathy", *The New England Journal of Medicine*, 326(19):1287-1288 (1992);
20. Atkinson, J. H. et al., "A Placebo-controlled Randomized Clinical Trial of Nortriptyline for Chronic Low Back Pain", *Pain*, 76: 287-296 (1998);
21. Mico, J. A., et al., "Analgesic, Sedative and Antidepressant Effects of Noradrenergic Antidepressants Related to Beta-Adrenoceptors", *European Neuropsychopharmacology*, S162, P.1.086, Abstract (1997);
22. Springer, J. P. et al., "Facilitatory and Inhibitory Effects of Selective Norepinephrine Reuptake Inhibitors on Hypogastric Nerve-Evoked Urethral Contractions in the Cat: A Prominent Role of Urethral  $\beta$ -Adrenergic Receptors", *The Journal of Urology*, 152: 515-519 (1984);
23. Dinan, T. G. et al., "Assessment of Central Noradrenergic Functioning in Irritable Bowel Syndrome Using a Neuroendocrine Challenge Test", *Journal of Psychosomatic Research*, 34(5): 575-580 (1990);
24. Leung, D. et al., "Protease Inhibitors: Current Status and Future Prospects", *J. Med Chem*, 43(3): 305-341 (2000);
25. O'Neill, M. J. et al., "Effects of  $\text{Ca}^{2+}$  and  $\text{Na}^{+}$  channel inhibitors in vitro and in global cerebral ischaemia in vivo", *European Journal of Pharmacology*, 332: 121-131 (1997);
26. Eisenach, J. C. et al., "Intrathecal, but Not Intravenous, Clonidine Reduces Experimental Thermal or Capsaicin-Induced Pain and Hyperalgesia in Normal Volunteers", *Anesth Analg*, 87: 591-596 (1998);
27. Marban, E. et al., "Structure and Function of Voltage-Gated Sodium Channels", *Journal of Physiology*, 508.3: 647-657 (1998);
28. Yanagawa, Y. et al., "A Novel Sodium Channel Inhibitor from *Conus geographus*: Purification, Structure, and Pharmacological Properties", *Biochemistry*, 27: 6256-6262 (1988);
29. Ryan, R., et al., "Evaluation of an Enkephalin Analog in Men with Castor Oil-Induced Diarrhea", *Clinical Pharmacol Ther*, 39(1): 40-42 (1986);
30. Penttila, O, et al., "Studies of Rectal Mucosal Catecholamines in Ulcerative Colitis", *Annals of Clinical Research*, 7: 32-36 (1975).

Applicants are submitting copies of Reference Numbers 1-9 and 14-30. In accordance with the waiver of 37 C.F.R. § 1.98 (a)(2)(i) in effect as of June 30, 2003, Applicants are not required to submit copies of the above-cited U.S. Patent Reference Numbers 10-13.

Inasmuch as this Information Disclosure Statement is being submitted in accordance with the schedule set out in 37 C.F.R. §1.97(b), no statement or fee is required.

Respectfully submitted,

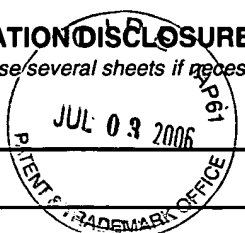
A handwritten signature in black ink, appearing to read 'Xiaochun Zhu', with a long horizontal flourish extending to the right.

Xiaochun Zhu  
Registration No. 56,311

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400 Garden City Plaza – Suite 300  
Garden City, New York 11530  
(516) 742-4343

XZ:ahs/ab

<b>INFORMATION DISCLOSURE CITATION</b> <i>(Use several sheets if necessary)</i>				ATTY DOCKET NO. <b>16096</b>		APPLICATION NO. <b>10/537,088</b>	
				APPLICANT(S) <b>Richard James Lewis et al.</b>			
				FILING DATE <b>June 2, 2005</b>		GROUP ART UNIT <b>Unassigned</b>	



U.S. PATENT DOCUMENTS							
*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
		6,767,896 B1	7/27/2004	McIntosh et al.			
		6,794,361 B1	9/21/2004	Lewis et al.			
		5,587,454	12/24/1996	Justice et al.			

U.S. PATENT APPLICATION PUBLICATIONS							
*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
		2005/0054827 A1	3/10/2005	Lewis et al.			

FOREIGN PATENT DOCUMENTS								
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
		WO 98/22126	5/28/1998	PCT				
		WO 91/07980	6/13/1991	PCT				
		WO 96/14079	5/17/1996	PCT				

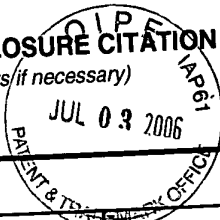
OTHER DOCUMENTS <i>(Including Author, Title, Date, Pertinent Pages, Etc.)</i>			
			Bowersox, S.S. et al., "Selective N-Type Neuronal Voltage-Sensitive Calcium Channel Blocker, SNX-111, Produces Spinal Antinociception in rat Models of Acute, Persistent and Neuropathic Pain", J. Pharmacol Exp. Ther., 279 (3): 1243-1249 (1996)
			Krames, Elliot S. et al., "Intrathecal D-Ala2-D-Leu5-enkephalin (DADL) Restores Analgesia in a Patient Analgetically Tolerant to Intrathecal Morphine Sulfate", Pain, 24: 205-209 (1986)

EXAMINER	DATE CONSIDERED
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

# INFORMATION DISCLOSURE CITATION

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Richard James Lewis et al.

FILING

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GROUP ART

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						YES	NO
	WO 96/40064	12/19/1996	PCT				
	WO 98/05309	2/12/1998	PCT				
	WO 98/02148	1/22/1998	PCT				
	WO 98/51668	11/19/1998	PCT				
	WO 97/30997	8/28/1997	PCT				

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

		Takagi, H. et al., "Analgesic Effect of L-threo-3-4-dihydroxyphenylserine (L-DOPS) in Patients with Chronic Pain", European Neuropsychopharmacology, 6: 43-47 (1996)
		Eisenach, C. et al., "Cerebrospinal Fluid Norepinephrine and Acetylcholine Concentrations During Acute Pain", Anesth Analg, 82: 621-626 (1996)
		Dubner, R. et al., "The Neurobiology of Pain and Its Modulation", The Clinical Journal of Pain, 5(Suppl 2): S1-S6 (1989)
		Dyck, P.J et al., "New Understanding and Treatment of Diabetic Neuropathy", The New England Journal of Medicine, 326(19):1287-1288 (1992)

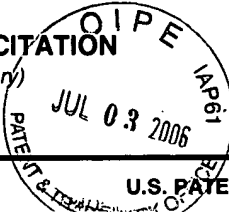
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				Richard James Lewis et al.			
				FILING <b>June 2, 2005</b>		GROUP ART <b>Unassigned</b>	



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							YES	NO
		WO 97/01351	1/16/1997	PCT				

**OTHER DOCUMENTS** *(Including Author, Title, Date, Pertinent Pages, Etc.)*

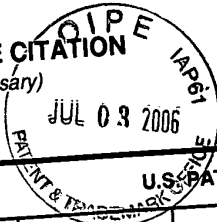
			Atkinson, J. H. et al., "A Placebo-controlled Randomized Clinical Trial of Nortriptyline for Chronic Low Back Pain", Pain, 76: 287-296 (1998)
			Mico, J. A., et al., "Analgesic, Sedative and Antidepressant Effects of Noradrenergic Antidepressants Related to Beta-Adrenoceptors", European Neuropsychopharmacology, S162, P.1.086, Abstract (1997)
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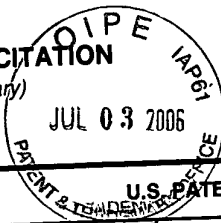
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		Marban, E. et al., "Structure and Function of Voltage-Gated Sodium Channels", Journal of Physiology, 508.3: 647-657 (1998)
		Yanagawa, Y. et al., "A Novel Sodium Channel Inhibitor from Conus geographus: Purification, Structure, and Pharmacological Properties", Biochemistry, 27: 6256-6262 (1988)
		Ryan, R., et al., "Evaluation of an Enkephalin Analog in Men with Castor Oil-Induced Diarrhea", Clinical Pharmacol Ther, 39(1): 40-42 (1986)
		Penttila, O, et al., "Studies of Rectal Mucosal Catecholamines in Ulcerative Colitis", Annals of Clinical Research, 7: 32-36 (1975)

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